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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,220	10/01/2004	Jose Ignacio Andres-Gil	JAB-1690	6227
27777	7590	09/27/2006	EXAMINER BERNHARDT, EMILY B	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			ART UNIT 1624	PAPER NUMBER

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/510,220

Applicant(s)

ANDRES-GIL ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-6,9,10,12,14,17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,9,10,12,14,17 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

In view of applicants' response filed 7/12/06 as well as earlier preliminary amendment filed on 10/1/04 the following applies.

Applicants' request for a recalculation of fees charged for multiple dependent claims originally present is noted. The PTO staff has indicated to the examiner that no fees were applied for claims 4-10,12,14 or 17 as they were in improper form.

Applicants are again reminded that the current BIB Data sheet lacks the foreign priority document mentioned in the oath.

Claims 1,2,4-6,9-10,12,14,17 and 18 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 6 was inadvertently not included in the previous rejection. With regard to "how to make" aspect of the rejection, applicants rely on reaction schemes on p.22-26 but these pages do not address the thrust of the rejection which is the making of **tetracyclic** cores, i.e. where R1 and R2 form rings together. Note the following passage in In re Howarth (previously cited) at p.690: "Applicants' risk in leaving anything out of

his application...burden rests upon applicant who chooses to rely upon general knowledge in art to render his disclosure enabling to establish that those of ordinary skill in the art can be expected to possess or know where to obtain this knowledge;" . Applicants' additional traverse is not persuasive. Describing the invention as broadly as it is claimed does not necessarily enable one how to make and use the invention. Literal support for the claims was also present in Surrey previously cited. If Surrey solely required literal support then the earlier Cauvallito decision (127 USPQ 202) would not have been heavily relied on as it was . Note the following quote taken from Cauvallito ( regarding literal support at p.205,left column: "The mere statement of an inventive concept, however, is not a sufficient basis for claiming it. Sufficient information must be given to enable those skilled in the art to practice the invention." . With regard to structure-sensitivity note the following quote at p.206, left column: "On the other hand, wide variation in such potency would suggest that it was due in part to the added substituents and might be eliminated or even reversed by many of the possible substituents which had not been tried." Thus as long ago as the Cauvallito decision, the emphasis on the need for working examples **representative** of the claims' scope was a requirement for compliance with 35 USC 112, par.one in unpredictable arts and the requirement is still present- see MPEP 2164.02. Given the recognized factors that can affect

receptor binding , namely size (surface area), polarity and electronic effects, the skilled artisan would **not** have sufficient information to predict what type of Het rings or other ring systems other than X as O from among the many covered by the instant scope would be suitable replacements for the small class of compounds made and tested. WO'484 while similar in having tricyclic cores with X as N or CH<sub>2</sub> lacks testing representative of above "Het" choices and I otherwise patentably distinct.

Also, contrary to what applicants state, there is no requirement that every Wands factor be deficient in order to conclude there is a lack of enablement. See MPEP 2164.04, p.2100-189, 2 May 2004 Ed. The examiner has not limited an analysis of the Wands factors to just one factor but rather many and based on the deficiencies that exist for most has considered "the evidence as a whole" weighing against enablement. For example, a recent Board decision, namely, Ex parte Varshavsky in 63 USPQ2d 1486, decided that a high level of skill in the art was not sufficient to override other Wands factors that demonstrated undue experimentation for the **full** scope claimed.

Claim 14 (which has been amended by preliminary amendment to statutory form) is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating anxiety and depression, does not reasonably

provide enablement for treating “body weight disorders”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Compounds are described to be  $\alpha$ -2 adrenoreceptor antagonists as well as selective serotonin reuptake inhibitors. While compounds having either mode of action are known as antidepressants, there is less known about eating disorders, or obesity which is covered by the rejected claim language. See for example Crow, provided with this action. In the “Expert Opinion” section, it is emphasized that there are many neurochemical systems that control eating. It is further stated: “At this point, it remains somewhat difficult to predict which one or several of these potential mechanisms will eventually yield effective treatments for eating disorders”.

Typos are noted. Note the spelling of “pyrrazolinyl” in the “Het” definition in claim 1 and 18.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The

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fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, appearing to read "Emily Bernhardt". The signature is written in a cursive, flowing style.

Emily Bernhardt  
Primary Examiner  
Art Unit 1624